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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,802	05/14/2001	Bojidar M. Stankov	1259-001	8869

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,802	STANKOV, BOJIDAR M.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18, 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

Amendment to page 8 appears to contain a typographical error in that after "1.65mg" there is a "- -".

Claims 17, 18, 20, 21, 22, 24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Said claims appear to not require the presence of a lubricant, however, claim 16 on which they are dependent recites the presence of a lubricant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16-18, 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the formulation set forth in Example 1, does not reasonably provide enablement for other formulations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to a tablet containing a slow release nucleus containing melatonin, hydroxypropylmethylcellulose (HPMC), lubricant, volume excipient and glidant and

a fast release coating on said nucleus containing melatonin, HPMC, lubricant, volume excipient and glidant and method of inducing and maintaining sleep, where at least 95% of the melatonin in the nucleus is released within 5 hours in an oscillating tray containing gastric/intestinal juice at 37 degrees Celsius, where at least 95% of the melatonin in the cortex is released within 10 minutes in an oscillating tray containing gastric/intestinal juice at 37 degrees Celsius and at least with said tablet having .

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record does not appear to disclose the claimed invention. Further, the prior art indicates that HPMC is a known retardant and dose of drug and amount and type of excipients all have an effect on release rates (See Bromet et al. (US Pat. 5,879,710), Column 5, lines 1-5; Lee et al. (1999), pages 74-77). Applicant argues that the prior art does not exhibit the release profile of the claimed invention as represented by Figure 1, yet the claimed invention also contains HPMC, a known retardant. As such, it appears that predictability in the art is low.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification appears to provide only one formulation which exhibits the release profile which applicant argues is the exhibited by the claimed invention.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that the only mentioned components are HPMC, melatonin, lubricant, volume excipient and glidant. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims, i.e. determining what combination of HPMC, melatonin, lubricants, volume excipients and glidants would result in the release profile claimed. Applicant

does not appear to address how the Amendment avoids the rejection herein. As such, the rejection is maintained.

Claims 16-18,20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant amends the claims to indicate that the slow release nucleus releases at least 95% of the melatonin within 5 hours in an oscillating tray containing gastric/intestinal juice at 37 degrees Celsius and at least 95% of the melatonin in the cortex is released within 10 minutes in an oscillating tray containing gastric/intestinal juice at 37 degrees Celsius.

Said limitation includes within its scope that at least 95% of melatonin is released from the nucleus in less than 5 hours and 95% of the melatonin is released from the cortex in less than 10 minutes. Applicant's disclosure only indicates that for the tablets tested 95% of the melatonin was released within the 5th hour not within five hours from the nucleus and in the tenth minute, not within ten minutes, at least 95% of the melatonin was released from the cortex (Pgs. 11, 12). Also, Applicant has amended the claims to indicate that the fast release cortex also contains a lubricant, volume excipient and glidant. However, the Specification does not appear to indicate that the "cortex" contains lubricant or a glidant. The only example set forth contains, in addition to melatonin and HPMC, lactose, a bulking agent, i.e. volume, titanium dioxide, a pigment, and ethyl alcohol and water, solvents, which presumably are evaporated away in order to form the cortex (See Pg. 8, lines 15-23).

Claims 16-18,20-24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the

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elements. See MPEP § 2172.01. The omitted elements are: (2) granulation, (4) addition of the retardant excipients, lubricants, volume and gliding excipients and (7) application of the melatonin solution under pressure on the tablets for the formation of the "cortex". Specification discloses that stages (2), (4) and (7) are essential for the preparation of the formulations which are the subject of the invention (Pg. 8, lines 27, 28).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Claims 17, 18, 20, 21, 22, 24 do not indicate the presence of a lubricant. Applicant argues that granulation and application of melatonin solution under pressure are descriptions of the best mode. However, the Specification does not indicate the same. The Specification explicitly states that granulation and application of melatonin solution under pressure are "essential".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


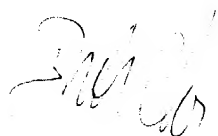
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571) 272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

November 27, 2004



JOHN PAK
PRIMARY EXAMINER
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